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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,739

02/19/2004

Shoichi Suzuki

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2170

2292

7590

04/14/2006

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/780,739	SUZUKI, SHOICHI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cynthia Collins	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on February 19, 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3,6,7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 2,3,6,7 and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/530,014.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/04, 10/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The preliminary amendment filed February 19, 2004 has been entered.

Claims 1, 4-5 and 8 are cancelled.

Claims 2, 3, 6, 7, 9 and 11 are currently amended.

Claims 14 and 15 are new.

Claims 2-3, 6-7 and 9-15 are pending and are examined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3, 6-7 and 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid having the nucleic acid sequence shown in SEQ ID NO:1 or 2, or a nucleic acid which hybridizes with the nucleic acid having the nucleotide sequence shown in SEQ ID NO: 1 or 2 under stringent conditions, or a nucleic acid having a homology of not less than 70% with the nucleotide sequence shown in SEQ ID NO:1 or 2, which sequences have a promoter activity in phloem tissue of a plant. The claims are also drawn to a recombinant vector and transformed plant comprising said nucleic acid.

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The specification describes SEQ ID NOS: 1 and 2 as polynucleotides that were obtained from *Urochloa panicoides* and that have promoter activity in phloem tissue of transgenic rice and maize plants (pages 6-13 *Examples 1 and 2*). The specification does not describe other sequences that are variants of SEQ ID NOS: 1 or 2 that have promoter activity in phloem tissue of a plant.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that “A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized variants of SEQ ID NOS: 1 and 2 that function as promoters in the phloem tissue of plants, nor the structural features unique to the genus.

Claims 2-3, 6-7 and 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid having the nucleic acid sequence shown in SEQ ID NO:1 or 2, does not reasonably provide enablement for other nucleic acids that are variants of SEQ ID NO:1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The claims are drawn to a nucleic acid having the nucleic acid sequence shown in SEQ ID NO:1 or 2, or a nucleic acid which hybridizes with the nucleic acid having the nucleotide sequence shown in SEQ ID NO: 1 or 2 under stringent conditions, or a nucleic acid having a homology of not less than 70% with the nucleotide sequence shown in SEQ ID NO:1 or 2, which sequences have a promoter activity in phloem tissue of a plant. The claims are also drawn to a recombinant vector and transformed plant comprising said nucleic acid.

The specification discloses how to obtain SEQ ID NOS: 1 and 2 from *Urochloa panicoides* and how to use SEQ ID NOS: 1 and 2 to drive the expression of operably linked sequences in the phloem tissue of transgenic rice and maize plants (pages 6-13 *Examples 1 and 2*). The specification does not disclose other sequences that are variants of SEQ ID NOS: 1 or 2 that have promoter activity in phloem tissue of a plant.

The full scope of the claimed invention is not enabled because it is unpredictable whether sequence variants of SEQ ID NOS: 1 and 2 would function as a promoter, or as a phloem-specific promoter, because basal and phloem-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the polynucleotide, which nucleotides and motifs may not be present in sequence variants of SEQ ID NOS: 1 and 2.

See, for example, Kim Y et al. (A 20 nucleotide upstream element is essential for the nopaline synthase (nos) promoter activity. *Plant Mol Biol.* 1994 Jan;24(1):105-17), who teach that various point mutations in the nos promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos*

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promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

See, for example, Guevara-Garcia A. et al. (Tissue-specific and wound-inducible pattern of expression of the mannopine synthase promoter is determined by the interaction between positive and negative cis- regulatory elements. *Plant J.* 1993 Sep;4(3):495-505), who teach that the pmas1' promoter of the *Agrobacterium* genes involved in mannopine synthesis is specifically expressed in phloem cells, and that this tissue-specific pattern of expression is the result of the interaction of at least two negative regulatory elements with a downstream positive element contained between promoter nucleotides -100 and -58 that directs expression in many cell types (abstract; page 496 Figure 1; paragraph spanning pages 497-498page 500 Figure 5; page 501 column 2).

In the instant case Applicant has not provided guidance with respect to the identity and location of key nucleotides and regulatory regions required for basal or phloem-specific promoter function, in SEQ ID NO:1 or SEQ ID NO:2 or their variants. Absent such guidance it would require undue experimentation for one skilled in the art to make and use sequence variants of SEQ ID NO:1 or SEQ ID NO:2, as one skilled in the art would have to isolated from undisclosed sources and/or synthesize variant nucleic acid sequences, and then test each sequence for phloem-specific promoter function in

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order to discriminate between operative and nonoperative sequences encompassed by the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 6, and claims dependent thereon, are indefinite in the recitation of "stringent conditions". It is unclear what conditions would yield the claimed nucleic acid molecules because those skilled in the art define "stringent conditions" differently.

***Allowable Subject Matter***

Claim 14-15 are allowed.

***Remarks***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Primary Examiner  
Art Unit 1638

CC

*Cynthia Collins*  
*4/7/06*